



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 1999

MEMORANDUM

Subject: Efficacy Review for 71871-R/CD-Cartridge Chlorine Dioxide Gas Generator

DP Barcode: D253229

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Applicant: Advanced Sterilization Products
Irvine, CA, USA

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Sodium Chlorite	72.8
<u>Inert Ingredient(s)</u>	27.2
Total	100.0

BACKGROUND:

Product manager has requested review of efficacy data (MRID No. 447417- 01) to support registration of CD - Cartridge as a generator of Chlorine Dioxide gas for industrial use

RECOMMENDATIONS: EASSB findings are:

Efficacy data submitted to test chlorine dioxide generated from CD - Cartridge (MRID No 447417-01) is **not acceptable** for the following reasons:

1. The study was not conducted in accordance with Good Laboratory Practice Standards (GLPS) issued under 40 CFR Part 160.
2. Submitted efficacy study was done according to FDA guidelines and does not meet EPA test requirements (DIS/TSS-9,AOAC Sporicidal Test) which state the following: "Sixty carriers-representing each of two types of surfaces are required to be tested against spores of both *Bacillus subtilis* and *Clostridium sporogenes* on three product samples representing three different batches, one of which is at least 60 days old."
3. Invalid sterility test results: EPA performance requirement for sterilizers mandate killing on all 720 carriers. No failures are permitted. Results presented in this study show growth in some of the processed cultures. Also, some unprocessed cultures showed no growth resulting in invalid sterility test results.

Note: The efficacy data (MRID No. 404678-01) for the substantially similar product, Scopas Sterilant Sysyem Cartirdge, EPA Reg. No. 56796-1, was not provided in support of this review.

(C:\copies of reviews\CD-Cartridge Chlorine Dioxide.wpd)